The Swiss Prison Study (SWIPS): Protocol for a public health registry among prisoners

Gaisl, Thomas ; Musli, Naser ; Baumgartner, Patrick ; Meier, Marc ; Rampini, Silvana K ; Blozik, Eva ; Battegay, Edouard ; Kohler, Malcolm ; Saxena, Shekhar

Abstract: Background: Health aspects, disease frequencies, and specific health interests of prisoners and refugees are poorly understood. Importantly, access to the healthcare system is limited for this vulnerable population. Objective: Currently, there has been no systematic investigation to understand the health issues of inmates in Switzerland. Furthermore, little is known on how recent migration flows in Europe may have impacted the health conditions of inmates in recent years. We therefore planned a large-scale observational study to establish a public health registry in northern-central Switzerland. Methods: Demographic and health-related data, such as age, sex, country of origin, duration of imprisonment, medication (including the drug name, brand, dosage, and release), medical history (including the ICD codes for all diagnoses and external results that are part of the medical history in the prison) will be deposited in a central register over a span of five years (April 2015 to April 2020). The final cohort is expected to comprise approximately 50,000 to 60,000 prisoners from the Police Prison Zurich (PPZ), Switzerland. The primary objective is to establish a central database to assess disease prevalence (i.e., ICD codes) among prisoners. The secondary objectives include the following: (1) to compare the 2015 to 2020 disease prevalence among inmates against a representative sample from the local resident population; (2) to assess longitudinal changes in disease prevalence from 2015 to 2020 using cross-sectional medical records from all inmates at the PPZ; and (3) to identify unrecognized health problems to prepare successful public health strategies. Results: The current study was funded in August 2020 by the ”Walter and Gertrud Siegenthaler” foundation and the ”Theodor and Ida Herzog-Egli” foundation and approved by the IRB in August 2019. Data collection started in August 2019 and results are expected to be published in 2021. Findings will be disseminated through scientific articles as well as presentations and public events. Conclusions: None Clinical Trial: ISRCTN registry (www.isrctn.com/ISRCTN11714665)

DOI: https://doi.org/10.2196/23973

The Swiss Prison Study (SWIPS): Protocol for a public health registry among prisoners

Thomas Gaisl, Naser Musli, Patrick Baumgartner, Marc Meier, Silvana K. Rampini, Eva Blozik, Edouard Battegay, Malcolm Kohler, Shekhar Saxena

Submitted to: JMIR Research Protocols
on: August 30, 2020

Table of Contents

Original Manuscript **5**
Supplementary Files **26**
..... **26**
Figures **27**
Figure 1 ..... **28**

The Swiss Prison Study (SWIPS): Protocol for a public health registry among prisoners

Thomas Gaisl[1, 2] MD; Naser Musli[1] MD; Patrick Baumgartner[1] BSc; Marc Meier[1] MD; Silvana K. Rampini[1] MD; Eva Blozik[3] MD; Edouard Battegay[1] MD; Malcolm Kohler[1] MD; Shekhar Saxena[2]

[1]University Hospital Zurich Zurich CH
[2]Harvard T H Chan School of Public Health Boston US
[3]Helsana Department of Health Sciences Zürich CH

Corresponding Author:
Thomas Gaisl MD
University Hospital Zurich
Rämistrasse 100
Zurich
CH

Abstract

Background: Health aspects, disease frequencies, and specific health interests of prisoners and refugees are poorly understood. Importantly, access to the healthcare system is limited for this vulnerable population.

Objective: Currently, there has been no systematic investigation to understand the health issues of inmates in Switzerland. Furthermore, little is known on how recent migration flows in Europe may have impacted the health conditions of inmates in recent years. We therefore planned a large-scale observational study to establish a public health registry in northern-central Switzerland.

Methods: Demographic and health-related data, such as age, sex, country of origin, duration of imprisonment, medication (including the drug name, brand, dosage, and release), medical history (including the ICD codes for all diagnoses and external results that are part of the medical history in the prison) will be deposited in a central register over a span of five years (April 2015 to April 2020). The final cohort is expected to comprise approximately 50,000 to 60,000 prisoners from the Police Prison Zurich (PPZ), Switzerland. The primary objective is to establish a central database to assess disease prevalence (i.e., ICD codes) among prisoners. The secondary objectives include the following: (1) to compare the 2015 to 2020 disease prevalence among inmates against a representative sample from the local resident population; (2) to assess longitudinal changes in disease prevalence from 2015 to 2020 using cross-sectional medical records from all inmates at the PPZ; and (3) to identify unrecognized health problems to prepare successful public health strategies.

Results: The current study was funded in August 2020 by the "Walter and Gertrud Siegenthaler" foundation and the "Theodor and Ida Herzog-Egli" foundation and approved by the IRB in August 2019. Data collection started in August 2019 and results are expected to be published in 2021. Findings will be disseminated through scientific articles as well as presentations and public events.

Conclusions: None Clinical Trial: ISRCTN registry (www.isrctn.com/ISRCTN11714665)

(JMIR Preprints 30/08/2020:23973)
DOI: https://doi.org/10.2196/preprints.23973

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**
Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v
Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

The Swiss Prison Study (SWIPS): Protocol for a public health registry among prisoners

Thomas Gaisl[1,2], Naser Musli[3], Patrick Baumgartner[2], Marc A. Meier[3], Silvana K. Rampini[3], Eva Blozik[4], Edouard Battegay[3], Malcolm Kohler[2], Shekhar Saxena[1]

[1] Global Health and Population, Harvard T H Chan School of Public Health, Boston, MA, USA

[2] Department of Pulmonology, University Hospital Zurich, Zurich, Switzerland

[3] Department of Internal Medicine, University Hospital Zurich, Zurich, Switzerland

[4] Department of Health Sciences, Helsana Insurance Group, Zürich, Switzerland

Corresponding author information

Thomas Gaisl, MD

Harvard T.H. Chan School of Public Health

677 Huntington Ave, Boston, MA

E-mail: thomasgaisl@hsph.harvard.edu

Abstract

Background. Health aspects, disease frequencies, and specific health interests of prisoners and refugees are poorly understood. Importantly, access to the healthcare system is limited for this vulnerable population. Currently, there has been no systematic investigation to understand the health issues of inmates in Switzerland. Furthermore, little is known on how recent migration flows in Europe may have impacted the health conditions of inmates.

Objectives. The Swiss Prison Study (SWIPS) is a large-scale observational study with the aim of establishing a public health registry in northern-central Switzerland. The primary objective is to establish a central database to assess disease prevalence (i.e., ICD-10 codes [German Modification]) among prisoners. The secondary objectives include the following: (1) to compare the 2015 to 2020 disease prevalence among inmates against a representative sample from the local resident population; (2) to assess longitudinal changes in disease prevalence from 2015 to 2020 using cross-sectional medical records from all inmates at the PPZ; and (3) to identify unrecognized health problems to prepare successful public health strategies.

Methods. Demographic and health-related data, such as age, sex, country of origin, duration of imprisonment, medication (including the drug name, brand, dosage, and release), medical history (including the ICD-10 codes [German Modification] for all diagnoses and external results that are part of the medical history in the prison) will be deposited in a central register over a span of five years (January 2015 to August 2020). The final cohort is expected to comprise approximately 50,000 to 60,000 prisoners from the Police Prison Zurich (PPZ), Switzerland.

Results. The current study was funded in August 2020 by the "Walter and Gertrud Siegenthaler" foundation and the "Theodor and Ida Herzog-Egli" foundation and approved by the IRB in August 2019. The study was registered with the ISRCTN registry (www.isrctn.com/ISRCTN11714665). Data collection started in August 2019 and results are expected to be published in 2021. Findings will be disseminated through scientific articles as well as presentations and public events.

Trial registration

ISRCTN registry (www.isrctn.com/ISRCTN11714665)

Introduction

In institutions such as prisons and correctional facilities, health risks are disproportionately widespread. It is estimated that approximately 6 million people are incarcerated every year in the World Health Organization (WHO) European Region.[1] The health profile of people in prison is complex and risk factors for poor health often overlap with risk factors for incarceration. [2] Co-occurring physical and mental health conditions are often found in close association to entrenched and intergenerational social disadvantage.[3] Data indicate that, in general, prisoners are sicker when compared with counterparts of the same age, race, and sex in free society.[4] Additionally, prisons and detention centers are known to reduce resources for inmates substantially, and disease frequencies and the health of individual prisoners are poorly understood owing to a lack of original data.[1] Finally, many inmates lack opportunities to articulate themselves (e.g. language barriers in Europe), and access to the healthcare system is extremely limited. Prison physicians often speak of a “blind spot in society.”[5] In contrast to the judicial branch which is obliged to publish numbers on the origin, age, sex, and penalties of convicts, systematic investigations on the health issues of inmates are extremely rare.

Current situation. Only a few prevalence studies conducted in the United States and Europe indicate that the disease profile of prison inmates is significantly different from that of the general population. In line with what is generally known about the health of people in prison, data from the Health in Prisons European Database (HIPED) paint a picture of an extremely vulnerable population that suffers from poor health and engages in risky health behaviors, leading to noncommunicable and communicable diseases and mental health conditions.[1, 6]

In this setting, drugs and non-medical use of conventional medications seem to play a crucial role in the health of people in prison.[6] In 2014, a report from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) suggested, that besides health-related problems, illicit drug use is highly prevalent among people in prison.[7] More recently, the EMCDDA has warned about the

rapidly developing phenomenon of the use of new psychoactive substances (NPS) among prisoners.[8] Monitoring data indicates, that prisons are the epicenter of a this phenomenon and there is growing concern that NPS may be responsible for a large share of drug-related problems in prison.[8] Approximately 4% to 56% of all inmates use psychoactive substances, but the exact percentage requires further investigation.[4, 9] For comparison, there is ample evidence that the “opioid crisis” in the United States affects inmates in particular.[10] Currently, only limited data from European institutions are available.[8] Studies conducted in the United States, estimate that the “off-label” usage of drugs in prisons is about 36.2%.[11] Once again, no comparable data from Switzerland are available and there seems to be a lack of systematically collected and comparable data on the health of incarcerated people.

In 2017, approximately 71% of prison inmates in Switzerland were foreigners and most were imprisoned in the Canton of Zurich.[12] One way of systematically recording specific aspects of disease burden in this population is to analyze medical files and histories. From past studies performed in the early 2000s, it has been established that analysis of medical records in prisons is an extremely reliable source. In fact, in some areas of disease burden (e.g. infections disease, assessment of cardiovascular risk) this can be considered superior to information gained from questionnaires or personal interviews.[9, 13] Most importantly, a systematic collection and analysis of medical records has not yet been conducted for inmates in Switzerland.

Police Prison Zurich (PPZ). Prison facilities are required to ensure adequate health care in both the somatic and psychiatric fields. When considering the PPZ, the University Hospital Zurich has taken over the responsibility for providing somatic and psychiatric care. The PPZ is the largest inmate correctional facility in Switzerland in Switzerland and approximately 10,000 to 12,000 prisoners are admitted per year. Data from the Federal Statistical Office in Switzerland indicate that inmates held for pre-trial detention are predominantly young, male, and approximately 75% are non-Swiss nationals (Figure 1). [12] Anecdotal evidence suggests that a large proportion of inmates (e.g., refugees, among others) have reported previously using drugs that were prescribed for off-label purposes. One example

is the prevalent purchase of the substance *pregabalin* via online pharmacies.[14] Other examples include the underestimated usage of recreational drugs (e.g., clonazepam) and other NPS.[15] Most of these drugs have potentially substantive health consequences, mainly attributed to their high potential for addiction and adverse effects. Furthermore, little information has been established on how recent refugee patterns may have impacted the health conditions of inmates in recent years.

Hypothesis. In summary, the prison population is very vulnerable; yet, hardly any reliable data is available on the health of inmates.[1, 3] The current geopolitical situation appears to exacerbate the problem as patients with a disproportionately poor health status have contact with the Swiss health care system. Data from the PPZ offers a unique opportunity globally for a representative analysis of the disease profile of inmates. The aim of this study is to collect health-related data in order to give insight into an unexplored area and underserved patient population.

We hypothesize (see Table 1) that the disease profile of inmates substantially differs from that of the general population. Specifically, certain chronic and psychiatric diseases are disproportionately prevalent among inmates and refugees. Second, a large number of drugs (e.g., NPS) may be used “off-label” and the origin of the inmates and the refugee route, respectively, may have an impact on the disease profile of the affected. Finally, recent geopolitical changes have significantly affected the overall disease profile of inmates.

Methods

Study design. This is an observational study with a population-based cross-sectional baseline measurement and no prospective follow-up.

Study objectives. The primary objective is to establish a central database to assess the prevalence of diseases (i.e., ICD-10 codes [German Modification]) among prisoners. The secondary objectives are (1) to compare the 2015 versus 2020 disease prevalence among inmates against a representative sample from the local resident population; (2) to assess longitudinal changes in disease prevalence from 2015 to 2020 using cross-sectional medical records from all inmates at the PPZ. Achieving these objectives promises to lead to new public health insights and the resulting database should allow for identification of unrecognized health problems to formulate models for successful public health strategies.

Study questions. The main questions under investigation include the following:

1. What is the health status of the inmate population and which conditions are over- and underrepresented in the prison setting? In particular, how do psychiatric diseases affect inmates and what is the estimated prevalence of substance abuse in the prison population? Which infectious diseases (e.g., tuberculosis, pneumonia, scabies, etc.) are highly prevalent among inmates and what are the comorbidities of this population.
2. What are the dynamics in the health profile of inmates (and thus refugees) during the European migrant crisis from 2015 onwards and how does the epidemiology of the prison population affect the balance between acute and chronic conditions?
3. Are there under-recognized health problems among vulnerable populations (e.g., children, pregnant mothers, patients with suicidal ideation), or overrepresented populations (e.g., body-packer, patients with traumatic injuries).

Study site. The health registry is based at the PPZ (Kasernenstrasse 29, 8021 Zurich, Switzerland). In this prison, all inmates of the Canton of Zurich are detained for up to a maximum of 7 days. Afterwards, prisoners are transferred to either 1) pre-trial detention, 2) serving a particular prison

sentence in a long-term facility, 3) anticipatory execution of sentence, or, 4) coercive measures are applied based on aliens law. The PPZ is the only central police prison in the Canton of Zurich serving a population of 1,520,968 (as of December 31, 2018), which is the most populous canton in the country. This prison has approximately 10,000 to 12,000 inmates yearly, of which about a third require medical attention (based on historical data from the PPZ / not published). The entire spectrum of medical attention needed to meet inmates' medical needs is covered within the PPZ, such as general internal medicine (e.g., asthma), traumatic injuries, psychiatric emergencies, and infectious diseases (e.g., HIV).

Participants. This study will enroll prisoners within the PPZ from April 1, 2015 until August 31, 2020. The final sample will be exhaustive. All inmates within this timeframe will be included in this study and there will be no random selection. Only in documented cases where a prisoner allegedly refuses to participate in health-related activities, they will be excluded from the study, and their data will not be analyzed. Otherwise, there are no exclusion criteria. Extrapolating from current numbers (approx. 850 prisoners per month x 64 months), it is expected that the final database will contain data from approximately 50,000 to 60,000 prisoners.

Cooperation. The study will be conducted in cooperation with the Cantonal Police Zurich (contact person: Ms. Iris Suter), the University Hospital Zurich which is the designated medical authority for the PPZ, and the Helsana AG (contact person: Dr. Eva Blozik). The Helsana AG is a major Swiss health insurance company with 2.1 million customers insured and will provide data on a matched Swiss cohort. Data will be extracted from the *Helsana Drug Report*[16], which is created in cooperation with the University Hospital Basel and the Institute for Pharmaceutical Medicine at the University of Basel. Another study site includes the University Hospital Zurich, Switzerland which contractually provides all outpatient and inpatient medical care for the PPZ, including psychiatric consultations. No other parties are involved in the medical care of the PPZ prisoners.

Data collection and management. Data entry into the health registry will be performed synchronously or asynchronously by a study team of physicians (T.G., N.M, P.B., M.M.) after carefully reviewing the source documents. A unique electronic case report form based on the variables in Table 2 and 3 was developed at the inception of this study. All source documents must be placed

within the medical history of the prisoner. Tables 2 and 3 summarize both the parameters and domains used in the study, which includes all variables, and other data extracted from the health registry. Unclear documentation will be discussed among the study team and incomplete data will be made apparent in the registry. After data entry, data will be checked for completeness and plausibility by the data manager. The database will be encrypted and only study personnel will have access to the source documents which will not leave the prison. Encrypted backups of the database will be periodically conducted using external hard drives.

Quality control. For this health registry, the following four quality control measurements will be implemented, and the results will be provided in the final manuscript:

1. Inter-observer variability: the source documentation of 150 random patients will be processed by two physicians (i.e. 450 degrees of freedom for every variable will be assessed) and disparities observed with regard to all domains (Tables 2 and 3) will be summarized.
2. Matching with a local database from the jurisdiction: data from the health registry will be compared with data from the jurisdiction, and discrepancies (e.g., country of origin, etc.) will be further investigated by the study team.
3. Internal validity: the consumption of medications will be summarized for each month from 2015 to 2020, and this data will be compared with the prescription data collected from the PPZ's local pharmacy which collects monthly data for all dispensed medication. This step ensures that the actually dispensed medication is equal to the prescribed medication.
4. Verification of the source documents: Foreign health-related documents must be checked and if necessary, translated to German by a recognized body (e.g., translation services). In case of an already established course of treatment pharmaceutical drugs with the dispensing category "A+", according to the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) article 24 (e.g., opioids, benzodiazepines methylphenidate, etc.), require an external verification of the original prescription and a statement from the physician. Written verifications by the federal authorities and/or non-governmental organizations involved in the opioid replacement therapy program will also be accepted. Other verifications by non-governmental organizations (e.g., refugee organizations) will not be accepted.

Data protection. In this registry, anonymized health data will be analyzed and stored. Other sensitive data, particularly religious, political, social security, or administrative data, will not be included as part of this study. The anonymized datasets generated and/or analyzed during the current study will be available upon request from T.G. Data are handled according to the Schengen Data Protection Act.

Statistical considerations. Statistical analyses will be conducted by the study team in consultation with senior statisticians. For baseline analyses, means or medians will be reported according to the distribution of the continuous variable. Proportions will be reported for categorical variables. For hypothesis testing, a t-test for normally distributed continuous variables and non-parametric tests for non-normally distributed continuous variables will be conducted; χ^2 testing will be used for categorical variables. Linear and/or logistic regression models with or without adjustment for potential confounders (i.e. age, sex, nationality) will be used when appropriate. Regression analysis estimates will be reported using 95% confidence intervals, and a two-sided p-value of <0.05 will be considered statistically significant for all reported tests. For the longitudinal data, a generalized linear mixed model with random effects (accounting for the nationality of the prisoner during the refugee crisis) will be used when appropriate. Statistical analyses will be performed using STATA Version 16 (StataCorp LP, College Station, TX).

Outcomes. The primary outcome measure will be disease prevalence using cross-sectional data from prisoner's medical records (i.e., using the ICD-10 codes [German Modification]) from 2015 to 2020. Secondary outcome measures include the following:

1. A comparison of disease prevalence (ICD-10 codes [German Modification]) of the inmates at the PPZ to a representative sample from the local resident population using cross-sectional medical records from all inmates at the PPZ from 2015 to 2020.
2. Longitudinal changes in disease prevalence (ICD-10 codes [German Modification]) from 2015 to 2020 using cross-sectional medical records from all inmates at the PPZ.

Ethical aspects. The study was approved by the Ethical Committee of the Canton of Zurich. The committee will be informed about major changes to the protocol in agreement with local requirements. The study will be conducted in accordance with the protocol and the principles enunciated in the current version of the Declaration of Helsinki, the guidelines of Good Clinical Practice issued by the

International Conference on Harmonization, and the requirements from the Swiss Law and Swiss regulatory authorities. The study protocol is reported according to the reporting adheres to SPIRIT guidelines, and results will be reported according to the STROBE statement from the University of Basel, Switzerland.

Results

The current study was funded in August 2020 by the "Walter and Gertrud Siegenthaler" foundation and the "Theodor and Ida Herzog-Egli" foundation and approved by the IRB in August 2019. Data collection started in August 2019 and results are expected to be published in 2021. Findings will be disseminated through scientific articles as well as presentations and public events.

Discussion

This health registry is designed to provide new public health insights into a group of vulnerable patients. The implementation of the study protocol promises to allow for the identification of specific health problems to help prepare successful public health strategies to meet these challenges. To gain a representative sample from the Canton of Zurich inmate population, this study required a high enrollment. Inmates at the PPZ usually spend a minimum of one day to a maximum of seven days in the facility, are internationally mobile, often unable to speak German, and have no contact details provided. Gaining informed consent from each prisoner is a disproportionately large expenditure. In this current observational study, we assume that the expected increase in knowledge will benefit future inmates and thus, outweigh the disadvantages associated with privacy concerns. Moreover, given these operational challenges, any large-scale study on the prisoner population will likely need to be conducted without receiving individualized informed written consent. Thus, in accordance with the Swiss Human Research Act article 34, the need to obtain informed consent is waived for this study and data collected from all prisoners will be gathered. Only in case of documented alleged refusal to participate in health-related activities, then data from the prisoner will not be included in this study.

Currently, no similar observational studies on Swiss inmates are available. Data from the United States

and European registries indicate, that prisoners are sicker when compared with counterparts in free society.[2-4] However, these data are limited to a certain location and time and they do not investigate changes over time within a certain cohort. Preliminary studies suggest, that illicit drugs and especially NPS are a growing problem in European prisons but only limited data from European prisons are available.[7,8] The current study will be able to draw conclusions on these issues based on a 5-year representative sample of approximately 50,000 to 60,000 prisoners from the PPZ. Thus, this study will add valid evidence to the current health status of prisoners and findings can be used to promote healthy behaviors (e.g. future intervention studies) and/or policy change for this population.

The findings of the study will be disseminated through peer-reviewed journals, as well as national and international conference presentations. Collaborations with other researchers in the field will be promoted. The data that support the findings of this study are available from the corresponding author, upon reasonable request. Furthermore, data will be presented to Swiss policymakers and healthcare workers to improve the public health of prisoners in Switzerland. In conclusion, the present study will construct a valuable database of information regarding the health of inmates and refugees and will act as groundwork for future interventions in this vulnerable population.

List of abbreviations

GCP	Good Clinical Practice
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
HIPED	Health in Prisons European Database
HRA	Swiss Human Research Act
ICD	International Classification of Diseases
NPS	New Psychoactive Substances
PPZ	Police Prison Zurich
SDPA	Schengen Data Protection Act
TPA	Therapeutic Products Act
WHO	World Health Organization

Declarations

Ethics approval and consent to participate. The study was approved on August 5th, 2019 by the Ethical Committee of the Canton of Zurich (Stampfenbachstr. 121 Postfach, 8090 Zurich, Switzerland; Phone +41 43 259 79 70; E-Mail admin.kek@kek.zh.ch) with the registration code KEK-ZH Nr. 2019-01055. The study will be conducted in accordance with the protocol and the principles enunciated in the current version of the Declaration of Helsinki, the guidelines of Good Clinical Practice issued by the International Conference on Harmonization, and the requirements from the Swiss Law and Swiss regulatory authorities. In accordance with the Swiss Human Research Act article 34, the need to obtain informed consent is waived for this study.

Consent for publication. Not applicable.

Availability of data and material. The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Funding. The study is supported by the Waltraud und Gertraud Siegenthaler fodundation and the Ida Herzog-Egli foundation (both in Zurich, Switzerland) via a personal grant to T.G. The funders of the study have no role in study design, data collection, data analysis, data interpretation, or writing of the manuscript.

Competing interests. T.G. and M.K. report consulting fees from Bayer AG, outside the submitted work. All other authors report no conflicts of interest.

Author Contributions. Study concept and design: T.G., M.K., and S.S. Drafting of the protocol: T.G. Critical revision of the manuscript for important intellectual content: all authors. Administrative, technical, or material support: all authors. Study supervision and funding: T.G., M.K., and S.S. All authors have read and approved the manuscript.

Acknowledgements. We would like to thank the foundations who supported this study and the Cantonal Police Force Zurich, for their collaboration. Without them, this study would have not been

possible.

References

1. World Health Organization. Regional Office for Europe. (2019). Status report on prison health in the WHO European Region. Regional Office for Europe. https://apps.who.int/iris/handle/10665/329943.
2. Marmot M: Inclusion health: addressing the causes of the causes. Lancet 2018, 391(10117):186-188. PMID: 29137870
3. Fazel S, Baillargeon J: The health of prisoners. Lancet 2011, 377(9769):956-965. PMID: 21093904
4. Stewart LA, Nolan A, Sapers J, Power J, Panaro L, Smith J: Chronic health conditions reported by male inmates newly admitted to Canadian federal penitentiaries. CMAJ Open 2015, 3(1):E97-E102. PMID: 25844377
5. Gesundheit im Gefängnis. Bundesamt für Gesundheit. spectra 91, 2018 https://www.bag.admin.ch/dam/bag/de/dokumente/mt/p-und-p/gefaegnisse/gesundheit-im-gefangnis.pdf.download.pdf/gesundheit-im-gefangnis.pdf
6. World Health Organization. Health in Prisons European Database (HIPED). Regional Office for Europe 2014. https://apps.who.int/gho/data/node.prisons
7. World Health Organization. Drug use in prison: assessment report. Regional Office for Europe 2014. https://www.emcdda.europa.eu/system/files/publications/784/Drug_use_in_prison_assessment_report_462763.pdf
8. World Health Organization. New psychoactive substances in prison (NPS). Rapid Communication of the European Monitoring Centre for Drugs and Drug Addiction. 2018. https://www.emcdda.europa.eu/system/files/publications/8869/nps-in-prison.pdf
9. Sahajian F, Berger-Vergiat A, Pot E: Use of psychoactive substances in prison: Results of a study in the Lyon-Corbas prison, France. Rev Epidemiol Sante Publique 2017, 65(5):361-367. PMID: 28886958
10. Barglow P: Commentary: The opioid overdose epidemic: Evidence-based interventions. The American journal on addictions / American Academy of Psychiatrists in Alcoholism and Addictions 2018, 27(8):605-607. PMID: 30311993
11. Brown GP, Stewart LA, Rabinowitz T, Boudreau H, Wright AJ: Approved and Off-Label Use of Prescribed Psychotropic Medications among Federal Canadian Inmates. Can J Psychiatry 2018, 63(10):683-691. PMID: 29706116
12. Swiss Federal Statistical Office. Platzierte und Inhaftierte - Bundesamt für Statistik. 2019 https://www.bfs.admin.ch/bfs/de/home/statistiken/kriminalitaet-strafrecht/justizvollzug/platzierte-inhaftierte.html
13. Bai JR, Mukherjee DV, Befus M, Apa Z, Lowy FD, Larson EL: Concordance between medical records and interview data in correctional facilities. BMC Med Res Methodol 2014, 14:50. PMID: 24716525
14. Schifano F, D'Offizi S, Piccione M, Corazza O, Deluca P, Davey Z, Di Melchiorre G, Di Furia L, Farre M, Flesland L et al: Is there a recreational misuse potential for pregabalin? Analysis of anecdotal online reports in comparison with related gabapentin and clonazepam data. Psychother Psychosom 2011, 80(2):118-122. PMID: 21212719
15. Vallersnes OM, Persett PS, Oiestad EL, Karinen R, Heyerdahl F, Hovda KE: Underestimated impact of novel psychoactive substances: laboratory confirmation of recreational drug toxicity in Oslo, Norway. Clin Toxicol (Phila) 2017, 55(7):636-644.

PMID: 28406320
16. Helsana insurance company. Helsana Drug Report 2018. https://www.helsana.ch/de/helsana-gruppe/ueber-uns/gesundheitswissenschaften/arzneimittelreport.html?d=s1092l1

Tables

Table 1. Hypothesis for the study protocol.

1.	The disease profile of inmates substantially differs from that of the general population. Specifically, certain chronic and psychiatric diseases are disproportionately prevalent among inmates and refugees.
2.	Recent geopolitical changes (e.g. refugee patterns) significantly affected the overall disease profile of inmates in the prisons.
3.	A large number of drugs (e.g. new psychoactive substances, NPS) may be used “off label” and their prevalence may be underestimated.

Table 2. Summary table of the general domains and parameters, which will be part of the registry.

Domain	Parameter	Comment
General characteristics		
Age, years	Years	at Baseline
Sex, (male, female)	Male / Female	
Date of imprisonment	Date	
Length of imprisonment	Days	
Country of origin	Sovereign state according to the United Nations	
Diagnosis		
Principal diagnosis	ICD-10 code	German Modification of the ICD
Secondary diagnosis (up to 20)	ICD-10 code	German Modification of the ICD
Medication		
Medication according to external documents	Active agent, dosage, administration	With external verification of drugs with dispensing category “A+”*
Every-day medication	Active agent, dosage, administration	With external verification of drugs with dispensing category “A+”*
On-demand medication	Active agent, dosage, administration	With external verification of drugs with dispensing category “A+”*

CT, computed tomography, ICD, International Classification of Diseases

* Category A+ according to the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) article 24 (e.g., opioids, benzodiazepines methylphenidate, etc.)

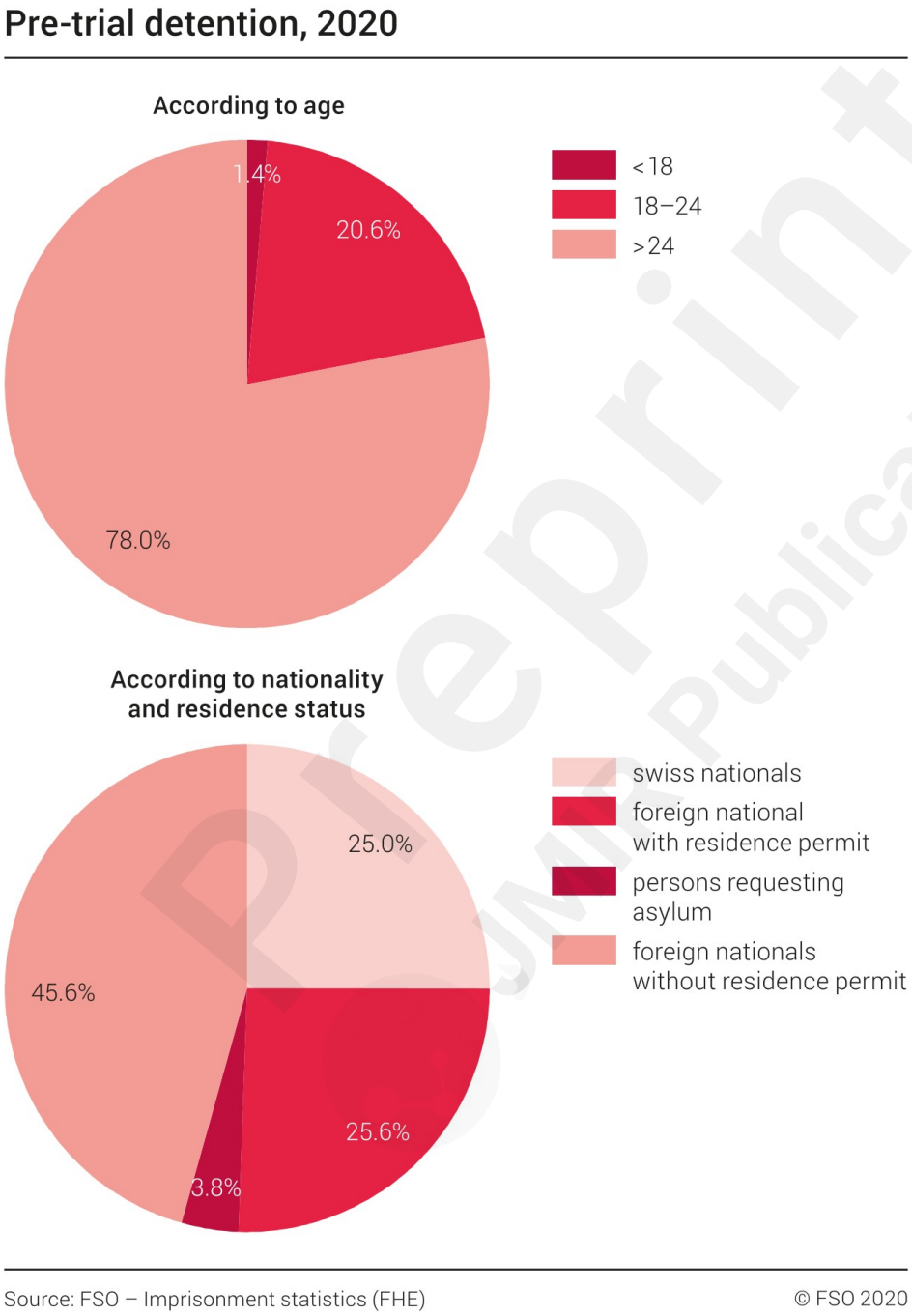
Table 3. Summary of the systematic characteristics which will be assessed in the registry.

Particular characteristics at admission		
Reason for consulting a physician during the imprisonment?	Text	
Evidence of a traumatic injury at admission?	Yes / No	If applicable: nature of the injury
Need for a “Hafterstehungsfähigkeit”* ?	Yes / No	
History of illicit drug abuse?	Yes / No	
Participant in the opioid replacement therapy program?	Yes / No	
History of benzodiazepine dependence?	Yes / No	
History of alcohol dependence?	Yes / No	According to the DSM-IV criteria
Result of the alcohol breath test at admission?	Milligram per Litre	optional
Evidence of body packing (according to CT scan results)?	Yes / No	
Particular characteristics during the imprisonment		
Need to consult a psychiatrist during imprisonment	Yes / No	
Admission to a hospital during imprisonment	Yes / No	
Special reports		
Blood pressure chart	Source document	optional
Blood sugar chart	Source document	optional
Medical history		
External documents	Source document	optional
Laboratory results (incl. pregnancy test)	Source document	optional

* “Hafterstehungsfähigkeit“ = initial 24/7 medical assessment by a physician which decides, whether the convict can be admitted to the prison in the first place

Figure titles

Figure 1. Insprisonment statistics for pre-trial detention in Switzerland 2020 from the Federal Statistical Office. [12]



Supplementary Files

Untitled.
URL: https://asset.jmir.pub/assets/ef0938199aad547c77bc7bd909ec39c1.docx

Figures

None.